



## UNITED STATES DEPARTMENT OF COMMERCE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/721,479 11/22/00 COIT

D PP01617.002

027476 HM12/1015  
CHIRON CORPORATION  
INTELLECTUAL PROPERTY - R440  
P.O. BOX 8097  
EMERYVILLE CA 94662-8097

 EXAMINER

BROWN, S

ART UNIT	PAPER NUMBER
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1648 *19*

DATE MAILED:

10/15/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

<b>Offic Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/721,479	COIT ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Stacy S Brown	1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 22 November 2000.
- 2a) This action is **FINAL**.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) \_\_\_\_\_ is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) 1-42 are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |   |  |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)            | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. . | 6) <input type="checkbox"/> Other: _____ .                                   |

### **DETAILED ACTION**

1. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to **Group Art Unit 1648**.
2. Applicant's amendment to the specification is acknowledged and entered.

#### ***Election/Restrictions***

3. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-19 and 32, drawn to an HCV polypeptide, classified in class 530, subclass 300.
  - II. Claims 20-31, drawn to an HCV polynucleotide, classified in class 514, subclass 44.
  - III. Claims 33-37, drawn to a method of preparing an HCV polypeptide, classified in class 435, subclass 70.1.
  - IV. Claims 38-40, drawn to an antibody that binds to an HCV polypeptide, classified in class 424, subclass 130.1.
  - V. Claim 41, drawn to a method of eliciting an immune response comprising administering a polypeptide, classified in class 424, subclass 184.1.
  - VI. Claim 42, drawn to a method of eliciting an immune response comprising administering a polynucleotide, classified in class 435, subclass 455.

The inventions are distinct, each from the other because of the following reasons:

- a) Inventions I, II and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the

different inventions are drawn to polypeptides, polynucleotides, and antibodies, having different structural and chemical properties, different modes of operation, function and effect. The polynucleotides and polypeptides are not disclosed as capable of use together. The antibodies are not disclosed as capable of use together with the polynucleotides.

- b) Inventions I and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the polypeptide can be chemically synthesized.
- c) Inventions I and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptides can be used in a materially different process of using such as in an antibody detection assay.
- d) Inventions I and VI are unrelated. The polypeptides of invention I are not required to practice the method of eliciting an immune response comprising administering a polynucleotide.
- e) Inventions II and (III and VI) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that

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product (MPEP § 806.05(h)). In the instant case the polynucleotides can be used in a materially different process of using such as in a method of preparing a polypeptide or in a method of eliciting an immune response.

f) Inventions II and V are unrelated. The polynucleotides of invention II are not required to practice the method of eliciting an immune response comprising administering a polypeptide.

g) Inventions IV and (III, V and VI) are unrelated. The antibodies of invention IV are not required to practice the methods of inventions III, V and VI, drawn to methods of preparing and using polypeptides and polynucleotides.

h) Inventions III, V and VI are all unrelated methods. The method of preparing an HCV polypeptide does not share method steps or reagents with the method of eliciting an immune response. The methods of eliciting an immune response with polypeptides and polynucleotides require different reagents. These methods have different modes of operation, function and effect, and are not disclosed as capable of use together.

Because these inventions are distinct for the reasons given above and the search required is burdensome, since the search for one group is not required or co-extensive for any other group, restriction for examination purposes as indicated is proper.

### ***Conclusion***

Papers relating to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 located in Crystal Mall 1. The Fax number for Art Unit 1648 is (703) 308-4426. All Group 1600 Fax machines will be available to receive

transmissions 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Stacy S. Brown, whose telephone number is (703) 308-2361. The Examiner can normally be reached on Monday through Friday and alternate Wednesdays from 6:30 AM-4:00 PM, (EST). If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, James C. Housel, can be reached at (703) 308-4027. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



HANKYEL T. PARK, PH.D  
PRIMARY EXAMINER

*Stacy S. Brown*  
Stacy S. Brown  
October 11, 2001